

**UNITED STATES DISTRICT COURT
FOR THE WESTER DISTRICT OF NORTH CAROLINA**

UNITED STATES OF AMERICA, <i>et al.</i> , <i>ex rel.</i> ANTONIO SAIDIANI Plaintiffs, v. NEXTCARE, INC., <i>et al.</i> , Defendants.	CIVIL ACTION NO. 3:11-cv-0141 FILED CHARLOTTE, NC JUN 12 2014 US District Court Western District of NC
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CONFIDENTIALITY AGREEMENT AND PROTECTIVE ORDER

WHEREAS, Relator Antonio Saidiani and Defendant John Shufeldt (individually, a “Party,” collectively, the “Parties”) are Parties to the above-referenced qui tam civil action, No. 3:11-cv-0141, including any appeals therefrom (collectively the “Litigation”);

WHEREAS, the Parties recognize that documents discoverable in this Litigation include “Protected Health Information” or “PHI,” as defined in 45 C.F.R. §160.103, promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”);

WHEREAS, the Parties recognize that other documents discoverable in this Litigation include or may include confidential information relating to sensitive business, financial, and proprietary information;

WHEREAS, the Parties seek to enable the flow of discovery materials between the Parties, facilitate the prompt resolution of disputes over confidentiality, adequately protect confidential information, including but not limited to Protected Health Information entitled to be kept confidential, and ensure that protection is afforded only to material so entitled;

NOW, THEREFORE, the Parties hereby stipulate and agree pursuant to Fed. R. Civ. P. 26(c), and for good cause shown, this Court hereby orders, as follows:

1. **Applicability Of This Stipulated Order.** This Stipulated Order shall govern all information, including documents and testimony, produced by any Party or non-party: a) in response to a discovery request (whether formal or informal), including but not limited to, deposition testimony and deposition transcripts, b) in response to a subpoena issued pursuant to the Federal Rules of Civil Procedure. This Stipulated Order concerns the treatment of confidential business information and documents containing such information, including but not limited to, financial, trade secret, marketing, customer research, development, proprietary, other commercial information, or other sensitive information that the producing party wishes to protect under this Consent Protective Order (hereinafter "Confidential Information"). Information may be designated as Confidential Information if it is sensitive and confidential business information that is (i) not available to the public, (ii) not readily determinable from public sources, and (iii) generally treated as confidential by a Party or witness. Information may also be designated as Confidential Information if it consists of or contains Protected Health Information, as further defined and described in the next paragraph.

2. **Production of Protected Health Information By The Parties That May Be Subject to 45 C.F.R. §§164.102-164.534, or Other Privacy Protections.** The parties and non-parties may produce certain Protected Health Information pursuant to discovery requests and/or subpoenas, etc. For the purposes of this protective order Protected Health includes, but is not limited to Individually identifiable health information as defined at 45 C.F.R. § 160.103, Medicare claims data, and data fields within Medicare claims data

that include a patient's name, address, telephone number, Social Security number or other identifying number, including Medicare HIC number.

The information produced pursuant to this Order may be subject to the provisions of 45 C.F.R. §164.102-164.534 and the patients may not have authorized the disclosure of such information. To the extent Protected Health Information is being disclosed, it is being produced in accordance with 45 C.F.R. §164.512(e)(1)(ii) and (v). These documents shall be produced unredacted and the producing Party shall designate such documents as Confidential Information in the manner set forth in paragraph 3, below, prior to producing them.

3. **Treatment of Protected Health Information By The Parties.** All Parties to this action are prohibited from using or disclosing Protected Health Information for any purpose other than the litigation of the above-styled action. At the conclusion of the litigation of this action, and subject to further order of this Court, all Parties to this action are required to destroy all copies of documents or material provided to them that contain Protected Health Information, or return the documents or material with Protected Health Information to the disclosing entity.

4. **Designation of Material Subject to this Protective Order.** To designate "confidential" material covered by this Protective Order, the producing Party shall so designate, on the material itself, in an accompanying cover letter, on a diskette cover, or interrogatory or request for admission response, by using the following designation: "CONFIDENTIAL INFORMATION-SUBJECT TO PROTECTIVE ORDER." Documents designated Confidential Information shall not be filed with or submitted to the Court nor shall their contents be reproduced in any court filing unless all Protected Health Information in the document or filing has been removed or redacted, or the filing is made

under seal. Unless otherwise agreed or ordered, this Order shall remain in force after dismissal or entry of final judgment not subject to further appeal.

5. **Access to Confidential Information.** Documents designated Confidential Information may be used by the Parties only for purposes of this litigation, and may be disclosed to witnesses, consultants, investigators and experts in this litigation (hereinafter “experts”), only as needed for the litigation. Further, if a disclosure is made to an expert under such circumstances, this expert will be required to review this Order prior to examining any documents containing Confidential Information and will be required to sign the form of acknowledgment attached to this Order.

Pursuant to 45 C.F.R. § 164.512(e)(1) and for purposes of HIPAA compliance, the Parties’ legal counsel in this action, and the employees and agents of each Party and each Party’s legal counsel in this action, are expressly and specifically authorized to provide Protected Health Information in accordance with this order to:

(a) respond to Interrogatories served pursuant to the Federal Rules of Civil Procedure in the above-styled action seeking Protected Health Information ;

(b) respond to Requests for Production of Documents, including electronically stored information, served pursuant to the Federal Rules of Civil Procedure in the above-styled action seeking Protected Health Information;

(c) respond to Requests for Admission served pursuant to the Federal Rules of Procedure in the above-styled action seeking Protected Health Information;

(d) request interviews or depositions and interview, depose, or respond in interviews or depositions in which Protected Health Information might be disclosed;

(e) disclose Protected Health Information to a Party's expert regardless of whether the expert is a consulting or testifying expert.

Pursuant to 45 C.F.R. § 164.512(e)(1) and for purposes of HIPAA compliance, each deponent noticed for deposition in the above-styled action, including but not limited to a Party, a fact witness, a records custodian, or an expert, is expressly and specifically authorized to use or to disclose to the Parties' legal counsel in this action and the employees and agents of each Party and each Party's legal counsel in this action the Protected Health Information that is responsive to deposition questions or a valid subpoena duces tecum.

Pursuant to 45 C.F.R. § 164.512(e)(1) and for purposes of HIPAA compliance, any person or entity authorized or ordered above to use or disclose Protected Health Information is expressly and specifically authorized to do so with, to, or before any court reporter service, videographer service, translation service, photocopy service, document management service, records management service, graphics service, or other such litigation service ("service providers"), designated by a Party or a Party's legal counsel in this case. The protections and requirements of paragraph 3 of this Stipulated Order apply to such service providers. Each Party or the Party's legal counsel is charged with obtaining advance consent of such service provider to comply with this paragraph. Upon such consent, the service provider will be deemed to have voluntarily submitted to this court's jurisdiction during the pendency of the above-styled action for purposes of enforcement of this paragraph, including but not limited to the imposition of such sanctions as may be appropriate for any non-compliance.

6. **Non-Parties.** Except as addressed in paragraph 4 above, non-parties shall not have access to material subject to this Protective Order. For example, although NextCare, Inc. ("NextCare") was a prior party to this litigation, it is no longer a party. As a non-party,

NextCare does not have access to material subject to this Protective Order unless that access is within the bounds described in paragraph 4.

7. **Inadvertent or Mistaken Productions Shall Not Waive Privilege or Protection.** If information subject to privilege or protection is inadvertently or mistakenly produced, such production shall in no way prejudice or otherwise constitute a waiver of, or estoppel as to, any claim of privilege or protection for such information as provided under applicable law, including Federal Rule of Evidence 502. If a producing Party has inadvertently or mistakenly produced information subject to a claim of protection or privilege, and if the producing Party makes a written request for the return of such information, the information for which a claim of inadvertent production is made (including any analyses, memoranda or notes which were internally generated based upon such inadvertently produced information), as well as all copies, shall be either destroyed or returned immediately to the producing party, even if the receiving Party disputes the claim of privilege. If the receiving Party disputes the producing party's assertion of privilege, the producing Party must submit the potentially privileged information to the Court for review in camera.

8. **Confidential Information in Depositions.** The Parties may show deponents documents designated Confidential Information to the extent the party deposing the witness determines that such documents are necessary for and relevant to the testimony of such witnesses. However, efforts should first be made, if practicable, to remove or redact all Protected Health Information in the document or filing. Any Party that wishes to designate pages of the transcript (and exhibits thereto) as Confidential Information must do so within 30 business days after receiving a deposition transcript. Confidential Information within the deposition transcript may be designated by underlining the portions of the pages that contain

Confidential Information and marking such pages with the following: "CONFIDENTIAL INFORMATION-SUBJECT TO PROTECTIVE ORDER." Until expiration of the 30-day period, the entire deposition will be treated as subject to protection against disclosure under this Protective Order. Following the Parties' designations of Confidential Information, only those portions of the deposition transcript and exhibits so designated will be treated as Confidential Information.

9. **Confidential Information in Open Court.** The procedures for use of documents containing material designated Confidential Information during any hearing or the trial of this matter shall be determined by the Parties and the Court in advance of the hearing or trial. The Parties shall consider redacting documents containing Confidential Information. With regard to Protected Health Information designated Confidential Information, the Parties shall consider coding the documents to substitute a numerical or other designation for the patient's name or other identifying information, requesting that any exhibit be placed under seal, introducing summary evidence where practicable which may be more easily redacted, and assuring that all Protected Health Information, including, but not limited to, the Social Security and HIC numbers associated with the names of individual patients, has been removed. No party shall disclose documents designated Confidential Information in open Court without prior consideration by the Court.

10. **Actions by the Court.** Applications to the Court for an order relating to any documents designated Confidential Information shall be by motion under Local Rules, LCrR55.1(D) (Sealed Records and Public Access) and any other procedures set forth in the presiding judge's standing orders or other relevant orders. Nothing in this Order or any action or agreement of a party under this Order limits the Court's power to make any orders

that may be appropriate with respect to the use and disclosure of any documents produced or use in discovery or at trial.

11. **Modification Permitted.** Nothing in this Order shall prevent any Party from seeking modification of this Order or from objecting to discovery that it believes to be otherwise improper.

12. **No Ruling on Discoverability or Admissibility.** This Protective Order does not constitute a ruling on the question of whether any particular material is properly discoverable or admissible and does not constitute a ruling on any potential objection to the discoverability of any material.

13. **Right to Challenge Designation.** Nothing in this Stipulated Order shall be construed in any way as a finding that information designated Confidential Information actually is Confidential Information. If a Receiving Party objects to the designation by a Producing Party, Designating Party, or participating non-party of any document or information as Confidential Information, the Receiving Party so objecting shall state the objection by letter to counsel of record for the Producing Party or Designating Party, or by letter to the designating non-party directly if no counsel has appeared on their behalf, and copy all counsel of record in this action. After providing this notice of objection, the Parties (and to the extent the challenged designation is made by a participating non-party, such non-party or its counsel) shall confer within fourteen (14) calendar days in an attempt to resolve the dispute regarding the designation of the documents or information. If the Parties are unable to resolve the dispute, the Receiving Party may within an additional thirty (30) calendar days move the Court to remove the Confidential Information designation. Until the Court rules on the motion, the relevant documents or information shall continue to be treated by each Receiving Party or participating

non-party as Confidential Information as designated by the Producing Party, Designating Party, or non-party.

14. **Information Designated as Confidential Held By The United States.** Nothing in this Stipulated Order shall prevent the United States from disclosing or limit or impair the United States' ability to disclose to any agency or department of the United States, or any division of any such agency or department, Confidential Information relating to any potential violation of law or regulation, or relating to any matter within that agency's jurisdiction, nor shall anything contained in this Stipulated Order prevent or in any way limit or impair the use of any Confidential Information by an agency in any proceeding relating to any potential violation of law or regulation, or relating to any matter within that agency's jurisdiction; provided, however, that the agency shall maintain the confidentiality of the Confidential Information consistent with the terms of this Stipulated Order.

Nothing in this Stipulated Order shall prevent the United States from disclosing or limit or impair the United States' ability to disclose Confidential Information obtained from a Party or non-party to a Congressional entity; provided, however, that the United States shall notify the Congressional entity requesting the Documents that the Confidential Information have been produced pursuant to this Stipulated Order and shall, if there are no objections interposed by the Congressional entity requesting the Documents, use a reasonable effort to notify the producing Party or non-party of the Congressional entity's request and the United States' responses thereto.

15. **Additional Procedures.** The parties agree to negotiate in good faith concerning any additional procedures that may be necessary to achieve compliance with HIPAA, its implementing regulations, and any other applicable federal or state law or regulation.

16. **Persons Bound.** This Order shall take effect when entered and shall be binding upon all counsel and their law firms, the parties, and persons made subject to this Order by its terms.

17. **Final Disposition of Confidential Information:** Disposition of Confidential material at the conclusion of the litigation shall be subject to further order of this Court.

AGREED TO BY THE PARTIES:

RELATOR ANTONIA SAIDIANI

JOHN SHUFELDT

By his attorneys,

By his attorneys,

By: _____
Daniel R. Miller, *pro hac vice* (PA Bar No.
68141)
Yael May, *pro hac vice* (PA Bar No. 307027)
BERGER & MONTAGUE, P.C.
1622 Locust Street
Philadelphia, PA 19103
(215) 875-3000
(215) 875-4604 – Fax
dmiller@bm.net
ymay@bm.net

By: _____
David Long
John W. O'Hale
Poyner Spruill LLP
P.O. Box 1801 (27602-1801)
301 Fayetteville St., Suite 1900
Raleigh, NC 27601
Tel. No. (919) 783-2802
Fax No. (919) 783-1075
dlong@poynerspruill.com
johale@poynerspruill.com

Clifford C. Marshall, Jr.
Marshall, Roth & Gregory, P.C.
P.O. Box 769
Asheville, North Carolina 28802
Telephone: (828) 281-2100
Email: cmarshall@mrglawfirm.com

SO ORDERED this 12th day of June, 2014

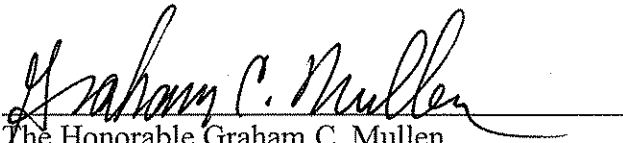

The Honorable Graham C. Mullen
United States District Judge

EXHIBIT A
UNITED STATES DISTRICT COURT
FOR THE WESTER DISTRICT OF NORTH CAROLINA

UNITED STATES OF AMERICA, <i>et al.</i> , <i>ex</i> <i>rel.</i> ANTONIO SAIDIANI Plaintiffs, v. NEXTCARE, INC., <i>et al.</i> , Defendants.	CIVIL ACTION NO. 3:11-cv-0141
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**ACKNOWLEDGMENT OF AND AGREEMENT
TO BE BOUND BY STIPULATED PROTECTIVE ORDER**

The undersigned hereby acknowledges that he/she has read the Stipulated Protective Order dated in the above-captioned action and attached hereto, understands the terms thereof, and agrees to be bound by its terms. The undersigned submits to the jurisdiction of the United States District Court for the Western District of North Carolina in matters relating to the Protective Order and understands that the terms of the Protective Order obligate him/her to use documents designated CONFIDENTIAL INFORMATION-SUBJECT TO PROTECTIVE ORDER in accordance with the Order solely for the purposes of the above-captioned action, and not to disclose any such documents or information derived directly therefrom to any other person, firm or concern.

The undersigned acknowledges that violation of the Stipulated Protective Order may result in penalties for contempt of court.

Name: _____

Job Title: _____

Employer _____

Business Address: _____

Dated: _____, 2014

Signature _____